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PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)	Group Art Unit:
Maor, et al.)	1617
Serial No.: 09/582,522)	Examiner:
)	Wells, L.
Filing Date: April 10, 2000)	
For: A GEL COMPOSITION FOR)	
SKIN CARE AND PROTECTION)	
AND A METHOD OF)	
PREPARATION THEREOF)	

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Commissioner for Patents
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DECLARATION #2 UNDER 37 C.F.R. § 1.132 OF SHLOMO MAGDASSI

I, Shlomo Magdassi of 36 Harnered Street, Jerusalem, Israel, an Israeli citizen declare hereinafter in writing as follows:

1. I am Associate Professor at the Hebrew University in Jerusalem.
2. My Curriculum Vitae was previously submitted in connection with the my first Declaration, filed November 26, 2003.
3. I am one of the inventors of the above captioned Application No. 09/582,522.
4. The present invention relates to a novel gel comprising at least Dead Sea water, a hydrophobic active agent, and a non-ionic solubilizer, wherein the gel is a clear gel.
5. It has been known in the art to provide a composition for the treatment of the skin that incorporates the therapeutic benefits of Dead Sea water and the moisturizing effects of hydrophobic active agents. See, e.g., Kyotaro, JP Abstract 08113530, which discloses a bath comprising Dead Sea water and hydrophobic active agents. Kyotaro does not discuss a gel composition, nor does it discuss how one would make a transparent gel composition.
6. In addition, it has been known to provide the high mineral content approximating Dead Sea water in a clear gel, although without the moisturizing effects of hydrophobic active

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agents. See, e.g., Biener, USP 4,943,432. Biener, however, disapproves of the use of actual Dead Sea water and does not disclose the use of hydrophobic active agents.

7. In spite of this knowledge, it was unknown how one could combine the positive effects of Dead Sea water with the positive effects of a hydrophobic active agent in a way that would produce a transparent gel. A transparent gel is an important goal because of its aesthetically pleasing properties.

8. Prior to the instant invention, attempts to combine Dead Sea water with hydrophobic active agents have led to the inevitable problem of precipitation. As a result of the precipitation the gel inevitably appeared cloudy or murky, and not aesthetically pleasing. This precipitation is believed to be caused by interaction of the ionic surfactant (present in the cosmetic product) with the multivalent electrolytes present in the dead sea, or dehydration, in the case on nonionic surfactants, again due to the high electrolytes content of the Dead sea. The turbidity may also result from a "salting out" effect, which is basically reduction of solubility due to the presence of electrolytes (mostly by dehydration), or, possibly through the interaction of the surfactant with the gelling agent.

9. Under my supervision, various attempts were made to solve the precipitation problem and obtain a transparent gel. These attempts included utilizing ionic surfactants (SDS, Cetrimonium chloride) which failed, and nonionic surfactants (Tween 80, Tween20) which gave no precipitation, at the first step without the hydrophobic active molecule. The results of these attempts are summarized below.

Solubilizer	Dead Sea Salt Con. [%/w]				
	0	10	20	30	Sat.
1.0% w/w SDS (anionic)	Transparent	Precipitate	Precipitate	Precipitate	Precipitate
3.0% w/w SDS (anionic)	Transparent	Precipitate	Precipitate	Precipitate	Precipitate
1.0% w/w Cetri Chloride (cationic)	Transparent	Precipitate	Precipitate	Precipitate	Precipitate
5.0% w/w Cetri Chloride (cationic)	Transparent	Precipitate	Precipitate	Precipitate	Precipitate
1.0% w/w Tween 20 (non-ionic)	Transparent	Transparent	Transparent	Transparent	Transparent
5.0% w/w Tween 20 (non-ionic)	Transparent	Transparent	Transparent	Transparent	Transparent
1.0% w/w Tween 80 (non-ionic)	Transparent	Transparent	Transparent	Transparent	Transparent
5.0% w/w Tween 80 (non-ionic)	Transparent	Transparent	Transparent	Transparent	Transparent

In the next stage, the two non-ionic solubilizers, (Tween 20 and Tween 80) were mixed with varying concentrations of the hydrophobic Vitamin E acetate, and varying concentrations of Dead

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Sea salt solutions and the results were expressed in units of NTU (Standard turbidity units, measured by a turbidimeter) wherein a transparent composition was considered a composition having a NTU below 100. The results are shown in Table 2 below.

10.

Solubilizer	Dead Sea Salt Con. [%/w]				
	0	10	20	30	Sat.
5.0% w/w Tween 20 + 0.4% w/w Vit. E-Ac.	9	7	10	16	16
5.0% w/w Tween 20 + 0.6% w/w Vit. E-Ac.	46	45	60	77	130
5.0% w/w Tween 20 + 0.8% w/w Vit. E-Ac.	62	141	150	165	160
5.0% w/w Tween 80 + 0.4% w/w Vit. E-Ac.	38	40	62	77	84
5.0% w/w Tween 80 + 0.6% w/w Vit. E-Ac.	40	82	80	89	91
5.0% w/w Tween 80 + 0.8% w/w Vit. E-Ac.	46	90	90	95	105

The results show that in all but saturated solutions of Dead Sea salts resulted in a transparent composition.

11. The results show in addition that the solubilizer Tween 80 having the longer chain is better capable of maintaining a transparent composition even with high Vitamin E acetate concentrations 0.8%.

12. Eventually, we made a composition comprising Dead Sea water, a hydrophobic agent, a gelling agent and non-ionic solubilizers. In particular, the composition we prepared contained: gelling agent: hydroxyethyl cellulose, active hydrophobic additive: Vitamin E acetate, Nonionic solubilizer: Arlaton 975 Arlaton 650 (PEG-36 and PEG 45 hydrogenated castor oil), and combinations of these surfactants with other nonionic solubilizers, Tween 20 and Tween 80. (table below)

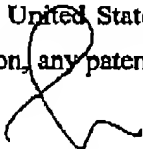
13. To our surprise, these compositions were clear gels.

14. Although the use of non-ionic solubilizers in cosmetic compositions is known, it was nowhere suggested that their use would solve the precipitation and turbidity problem. References such as Thompson, USP 5,425,954, which disclose cosmetic compositions comprising non-ionic solubilizers, failed to teach or suggest the success of our composition. In particular, Thompson did not reference Dead Sea water or the "salting out" and precipitation problems. Thus, I would not have looked to Thompson to find an additive that could be favorably combined with both a

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hydrophobic agent and Dead Sea water, as there is no motivation to combine the non-ionic solubilizer in Thompson with the Dead Sea water of Biener or the Dead Sea water and hydrophobic agent of Kyotaro.

11. I hereby declare that all statements made herein of my own knowledge and are based on the Master's thesis of Y. Shaul, are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that willful false statements may jeopardize the validity of the Application, any patent issuing thereof, or any patent to which this verified statement is directed.



Shlomo Magdassi

Executed this 5 day of 5 July_____, 2004.

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Compositions of transparent gels with dead sea salt. For each salt concentration the turbidity is given by NTU

הקצרים	Dead Sea Salt Con. [%/w/w]				
	0	10	20	30	Sat.
3.0%/w/w Arlatone 650 + 0.4%/w/w Vit. E-Ac.	22	32	33	30	34
3.0%/w/w Arlatone 650 + 0.6%/w/w Vit. E-Ac.	23	34	36	40	42
3.0%/w/w Arlatone 650 + 0.8%/w/w Vit. E-Ac.	25	33	40	44	48
1.5% Arlatone 650 + 1.5% Tween 20 + 0.4% Vit. E-Ac.	9	11	11	9	6
1.5% Arlatone 650 + 1.5% Tween 20 + 0.6% Vit. E-Ac.	16	17	16	14	14
1.5% Arlatone 650 + 1.5% Tween 20 + 0.8% Vit. E-Ac.	30	24	24	26	22
1.5% Arlatone 650 + 1.5% Tween 80 + 0.4% Vit. E-Ac.	10	18	18	10	10
1.5% Arlatone 650 + 1.5% Tween 80 + 0.6% Vit. E-Ac.	13	14	16	12	16
1.5% Arlatone 650 + 1.5% Tween 80 + 0.6% Vit. E-Ac.	42	26	29	30	39
3.0%/w/w Arlatone 975 + 0.4%/w/w Vit. E-Ac.	40	55	38	33	36
3.0%/w/w Arlatone 975 + 0.6%/w/w Vit. E-Ac.	47	68	46	43	41
3.0%/w/w Arlatone 975 + 0.8%/w/w Vit. E-Ac.	70	92	65	60	63
1.5% Arlatone 975 + 1.5% Tween 20 + 0.4% Vit. E-Ac.	11	11	8	8	9
1.5% Arlatone 975 + 1.5% Tween 20 + 0.6% Vit. E-Ac.	15	18	16	16	16
1.5% Arlatone 975 + 1.5% Tween 20 + 0.8% Vit. E-Ac.	46	20	21	22	25
1.5% Arlatone 975 + 1.5% Tween 80 + 0.4% Vit. E-Ac.	17	13	10	9	11
1.5% Arlatone 975 + 1.5% Tween 80 + 0.6% Vit. E-Ac.	20	14	15	16	16
1.5% Arlatone 975 + 1.5% Tween 80 + 0.6% Vit. E-Ac.	22	37	35	33	33